MAR 2 5 2010

Section 6- 510(k) Summary

a. Company name, address

NIKKISO CO., LTD.
Medical Equipment Unit
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Shizuoka, 421-0496, Japan

b. Contact

Hachiro Edamura
Manager of Quality Control

c. Date prepared

June 19, 2009

d. Name of device

Trade Name:	DBB-06 HEMODIALYSIS DELIVERY SYSTEM
Common Name:	High Permeability Hemodialyzer
Classification Name:	Dialyzer, High Permeability With or Without Sealed Dialysate System

e. Predicate devices

The DBB-06 HEMODIALYSIS DELIVERY SYSTEM is substantially equivalent to:

510(k):	K023509
Trade name:	DBB-05 Hemodialysis Delivery System
Product code:	KDI

510(k):	K061519
Trade name:	Modification to DBB-05 Hemodialysis Delivery System
Product code:	KDI

f. Description of the device

The DBB-06 HEMODIALYSIS DELIVERY SYSTEM is composed of a hydraulic unit for the delivery of dialysate and extracorporeal blood circuitry. The permeate is heated and deaerated in the hydraulic section, which is then mixed with concentrate and fed into the dialyzer through the dialysate fluid feeder. The closed balancing system assures the amount of dialysate infused corresponds to the amount of dialysate extracted. The interior pressure of the dialyzer is controlled automatically by adjustment of the ultra filtration amount and UF rate by the dialyzer. Heparinization of the external circulating blood is accomplished with the heparin pump either by continuous or bolus injection before it is passed on to the dialyzer.

The DBB-06 HEMODIALYSIS DELIVERY SYSTEM uses both acetate dialysis and bicarbonate dialysis. Utilizing the various functions of the device, the conductivity and UF profile can be programmed. In addition, the device incorporates all functions necessary for double-needle dialysis as well as single-needle dialysis procedures. The hydraulic unit is cleaned and disinfected using selectable cleaning programs and is equipped with protective systems for patient safety and proper operation.

A Blood Volume Monitor (BVM) is an optional accessory available for the DBB-06 HEMODIALYSIS DELIVERY SYSTEM, and was not available with the predicate device, the DBB-05 Hemodialysis Delivery System. The BVM monitors blood volume to assist in the prevention of excessive removal of fluid.

g. Indications for Use

Indication for Use
The DBB-06 Hemodialysis Delivery System is indicated for hemodialysis prescribed by physicians for adult patients with acute and chronic renal failure, treated in hospitals and dialysis clinics by qualified operators. The DBB-06 Hemodialysis Delivery System is not indicated for pediatric patients. It is not for home use.

h. Statement of substantial equivalence
The DBB-06 HEMODIALYSIS DELIVERY SYSTEM is substantially equivalent to the DBB-05 Hemodialysis Delivery System (K023509) and the Modification to DBB-05 Hemodialysis Delivery System (K061519).

Table 1 below compares the DBB-06 HEMODIALYSIS DELIVERY SYSTEM to the DBB-05 Hemodialysis Delivery System (K023509) and the Modification to DBB-05 Hemodialysis Delivery System (K061519). All three devices are totally self-contained machines and include:

- the same Indication for Use
- use the same Operating Principle
- incorporate the same Basic System Design
- automatic priming of the extracorporeal circuit
- prepare dialysate
- monitors for the dialysate and blood
- pumps for blood and anticoagulant (heparin) at predetermined rates
- controls fluid removal
- automatically cleans, disinfects, and rinses the dialysate flow path
- incorporate the same materials

Table 1. Comparison table of DBB-05 and DBB-06 Device Characteristics

Device Characteristics	PREDICATES		PROPOSED
	Nikkiso DBB-05 Hemodialysis Delivery System (K023509)	Modification to Nikkiso DBB-05 Hemodialysis Delivery System (K061519)	Nikkiso DBB-06 Hemodialysis Delivery System
Product Code	KDI	Same	Same
Indications for Use	The DBB-05 Hemodialysis Delivery System is indicated for hemodialysis prescribed by physicians for adult and pediatric patients with acute or chronic renal failure. The DBB-05 is intended for hemodialysis performed in hospitals and dialysis clinics by a qualified operator.	Same	Same adult indication for use
Proportioning system	Continuous volumetric dilution with duplex pump	Same	Same
Temperature control (°C)	34 to 40	Same	Same
Temperature alarm limit (°C)	Fixed: 33, 41 Auto: ±1 from set value[1]	Same	Same
Bicarbonate conductivity range (mS/cm)	2.30 to 7.00	Same	Same
Total conductivity range (mS/cm)	12.5 to 15.5	Same	Same
Flow (mL/min)	0, 300 to 800	Same	Same
Transmembrane pressure (mmHg)	-100 to +500	Same	Same
Sodium therapy	Yes, Profiled	Same	Same
Ultrafiltration removal rate (L/h)	0.00; 0.10 to 4.00, Profiled UF	Same	Same
PH monitor	None	Same	Same

Device Characteristics	PREDICATES		PROPOSED
	Nikkiso DBB-05 Hemodialysis Delivery System (K023509)	Modification to Nikkiso DBB-05 Hemodialysis Delivery System (K061519)	Nikkiso DBB-06 Hemodialysis Delivery System
BYPASS INDICATOR	Visual	Same	Same
BLOOD CIRCUIT			
Arterial pressure (mmHg)	-300 to +300	Same	Same
Venous pressure (mmHg)	-200 to +500	Same	Same
Blood pump range (mL/min)	40 to 600	Same	Same
Heparin pump range (mL/h)	0.0 to 9.9 (10, 20, 30 mL syringe)	Same	Same
DISINFECTION	Chemical, thermo-chemical, hot rinse	Same	Same
DISPLAY TYPE	LCD, 12.1" color, SVGA	Same	Same
DISPLAY PARAMETERS			
Dialysate pressure	Yes	Same	Same
Transmembrane pressure	Yes	Same	Same
Bicarbonate conductivity	Yes[2]	Same	Same
Total conductivity	Yes	Same	Same
Flow rate	Yes	Same	Same
Elapsed time	Yes	Same	Same
Remaining time	Yes	Same	Same
Complete time	Yes	Same	Same
Kt/V ratio calculation display	No	Yes	Yes
Blood pressure value history	Numeric	Numeric or Graphical	Numeric or Graphical
Blood volume	No	No	Yes
MICROPROCESSOR			
Type	3 microprocessor system, TX1941AF Toshiba, 32bit.	Same	Same
Storage	Treatment data	Same	Same

Device Characteristics	PREDICATES		PROPOSED
	Nikkiso DBB-05 Hemodialysis Delivery System (K023509)	Modification to Nikkiso DBB-05 Hemodialysis Delivery System (K061519)	Nikkiso DBB-06 Hemodialysis Delivery System
Interface	Built-in RS-232 for technician, Optional TCP/IP for network system.	Same	Same
LOSS-OF-WATER ALARM	Yes	Same	Same
OTHER SPECIFICATION			
Single needle Click-Clack	Yes	Same	Same
Arterial clamp for use during Single needle Click-Clack	No	Yes	Yes
Bicarbonate concentrate type	Liquid	Liquid or Dry Powder	Liquid or Dry Powder
Built in BP monitoring	Yes	Same	Same
Isolation UF	Yes	Same	Same
Online UF control test	Yes, Continuously[3]	Same	Same
Built in Blood Volume Monitor (BVM)	No	No	Yes

Notes:

1. The dialysate temperature alarm limit is set to ±1°C from the temperature target value automatically. The alarm window ±1°C can be changed from 0 to ±5°C.
2. The maximum concentrate deviation alarm limit is set at ±3%.
3. Specification of online UF control test.

New optional accessories

Blood Volume Monitor (BVM)

A Blood Volume Monitor (BVM) is a new optional accessory available with the DBB-06 HEMODIALYSIS DELIVERY SYSTEM, which was not available in the predicate devices; the DBB-05 Hemodialysis Delivery System (K023509) and the Modification to DBB-05 Hemodialysis Delivery System (K061519).

The predicate device used to determine substantial equivalence to the Blood Volume Monitor (BVM) was the CRIT-LINE Monitor III (CLMIII) (K972470). Both the Blood Volume Monitor (BVM) and the CRIT-LINE Monitor III (CLMIII) (K972470) are identical in function and operate under the same principle of light absorption passing through the blood under test, to measure hematocrit and calculate the related value of blood volume.

Following is comparison table for the Blood Volume Monitor of DBB-06 and the CRIT-LINE Monitor III (K972470);

Table 2 BVM Comparison Table

Item	Predicate Device CRIT-LINE Monitor III (K972470)	DBB-06 Blood Volume Monitor
Intended Use	Used for non-invasive hematocrit, oxygen saturation and blood volume monitoring. Percent change in blood volume in real time application in the treatment of dialysis patients with intended purpose of providing a more effective treatment for the dialysis patient. Based on the data that the monitors provide, the dialysis technician increases or decreases the rate at which fluid is removed from the blood in order to remove the maximum amount of fluid from the dialysis patient without the patient experiencing the common symptoms of dialysis which include nausea, cramping and vomiting.	Used for non-invasive blood volume monitoring. This monitoring provides the percent change in blood volume in real time. The healthcare provider may increase or decrease the rate at which fluid is removed from the blood based on the data that blood volume monitor provides.
Technological Characteristics		
Principle of blood volume monitoring	The device functions and operates under the principles of light absorption through the blood to calculate the relative value of Blood Volume (BV).	The device functions and operates under the principles of light absorption through the blood to calculate the relative value of Blood Volume (BV).
Microprocessor control	Yes	Yes

The measurement is accomplished by calibrated Analog to Digital Converters (ADC).	Yes	Yes
Accuracy	Approximately +/-2% and compare well with other methods such as centrifuge.	Approximately +/-2% and compare well with other methods such as centrifuge.
Clinical testing	No clinical testing was performed. Comparison testing was performed on blood bank blood under simulated conditions.	Clinical Test was performed

Based on the technical characteristics, performance and failure simulation testing of the Blood Volume Monitor (BVM), NIKKISO CO., LTD. concludes that the Blood Volume Monitor (BVM) performed as well as and is substantially equivalent to the CRIT-LINE Monitor III (CLMIII) (K972470) and does not raise any new questions regarding safety or effectiveness.

Non-Invasive Blood Pressure (NIBP) measurement module

A Non-Invasive Blood Pressure (NIBP) measurement module is an optional accessory used to monitor the patient's blood pressure during hemodialysis treatment. The DBB-05 Hemodialysis Delivery System (K023509) and the Modification to DBB-05 Hemodialysis Delivery System (K061519) both use the Omron Colin Model M2100 NIBP. The DBB-06 HEMODIALYSIS DELIVERY SYSTEM uses a newer model, the Omron Colin Model M2500 NIBP. The manufacturer for both models is Omron Colin Co., Ltd., 1-12-14 Koishikawa, Bunkyo-ku, Tokyo Japan.

The M2500 is integrated into a variety of patient monitors worldwide and is used to measure patient blood pressure using the oscillometric method with a standard blood pressure cuff wrapped on the patient's upper arm. The M2500 consists of the following four major hardware and software blocks:

- Cuff pressure control hardware block
- Cuff pressure detection and pulse detection hardware block
- Cuff pressure and pulse amplitude data set generation block
- Blood pressure determination block

The M2100 was developed using similar technology of the predicate device, the Press-Mate Advantage (K973637). All three (3) NIBPs, the M2500, M2100 and the Press-Mate Advantage are manufactured by Colin Corporation, which merged with Omron Group creating the new company Omron Colin Co., Ltd.

Following is comparison table of the M2500, M2100 and the Press-Mate Advantage.

Table 3 comparison table of the M2500, M2100 and the Press-Mate Advantage.

No.	Item	M2500 NIBP for DBB-06 (K091978) under application	M2100 NIBP for DBB-05 (K023509) and modified DBB-05 (K061519)	Press-Mate Advantage (K973637)
1	Cuff (Arm circumference range)	12～40cm	Same	10～66cm
2	Cuff Biocompatibility	Compliant	Compliant	Compliant
3	IEC60601-2-30:1999	Compliant	Compliant	IEC60601-2-30:1995
4	EN1060-1:1995	Compliant	Compliant	Compliant
5	EN1060-3:1997	Compliant	Compliant	Compliant
6	ANSI/AAMI SP-10 for NIBP Measurement	Compliant	Compliant	Compliant
7	Measuring range and Accuracy	0 to 300mmH Within +/-3mmHg	0 to 300mmH Within +/-3mmHg	0 to 300mmH Within +/-3mmHg
8	Power supply	DC 12 V	DC 12 V	-*
9	Pin assigns	3 Signal Pins and 7 Power supply pins	3 Signal Pins and 7 Power supply pins	-*
10	Technical Alarms	12 types of alarms (C11-21)	12 types of alarms (C11-21)	12 types of alarms (C11-21)
11	Fatal Alarms	4 types of alarms(E03, E07, E08,E09)	4 types of alarms(E03, E07, E08,E09)	4 types of alarms(E03, E07, E08,E09)
12	Software algorithms	Same	Same	Same

*: Device is an all-in-one vital signs monitor with NIBP, and is not connected to another device.

As shown in the above comparison table as well as in the performance test in those blood pressure monitors, it is demonstrated that M2500 is substantially equivalent to the M2100 used in the predicate devices, the DBB-05 Hemodialysis Delivery System (K023509) and the Modification to DBB-05 Hemodialysis Delivery System (K061519) and to Press-Mate Advantage, and does not raise any new questions regarding safety or effectiveness.

i. Conclusion

Based on the above discussion and enclosed sections regarding substantial equivalence to predicate devices, NIKKISO CO., LTD. concludes that the DBB-06 HEMODIALYSIS DELIVERY SYSTEM is substantially equivalent to the DBB-05 Hemodialysis Delivery System (k023509) and the Modification to DBB-05 Hemodialysis Delivery System (k061519), and does not raise any new questions regarding safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
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JAPAN

MAR 25 2010

Re: K091978
Trade/Device Name: DBB-06 Hemodialysis Delivery System
Regulation Number: 21 CFR §876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Codes: KDI
Dated: March 19, 2010
Received: March 22, 2010

Dear Dr. Kanai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive, Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (If known): K091978

Device Name: DBB-06 HEMODIALYSIS SYSTEM

Indication for Use

The DBB-06 Hemodialysis Delivery System is indicated for hemodialysis prescribed by physicians for adult patients with acute and chronic renal failure, treated in hospitals and dialysis clinics by qualified operators.

The DBB-06 Hemodialysis Delivery System is not indicated for pediatric patients. It is not for home use.

Prescription Use X
(Per 21 CFR 801 Subpart D)

AND/OR

Over-the Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K091978

ATTACHMENT QUESTION 1, 2, and 3